--Yet another object is to provide color and visual images and effects for food products and for pharmaceuticals, (1) without the use of FDA regulated colors, dyes, inks, or metals, or (2) with colors other than those which are FDA approved, or (3) with the use of FDA approved colorant only as a contrast color to make holographic effects and images more readily visible.--

A2

Please replace the paragraph beginning at page 5, line 17, with the following rewritten paragraph:

--a thermoformable solid outer layer overlaying said core, and a microrelief in said layer.--

A3

Please replace the paragraph beginning at page 5, line 23, with the following rewritten paragraph:

--~~This layer is formed from~~ an aqueous solution of a thermoformable material selected from the group consisting of modified cellulose, modified food starch, gelatin, waxes, vegetable gums, and combinations thereof. The preferred material comprises a modified cellulose, namely, hydroxypropylmethylcellulose (HPMC), hydroxypropylcellulose (HPC), and mixtures thereof.--

A4

Please replace the paragraph beginning at page 6, line 26. with the following rewritten paragraph:

--a conveyor that carries the coated cores in a first direction,--

A5

Please replace the paragraph beginning at page 7, line 13, with the following rewritten paragraph:

--Fig. 2B is a view in side elevation of the tablet shown in Figs. 2 and 2A;--

A6

Please replace the paragraph beginning at page 9, line 15, with the following rewritten paragraph:

--Fig. 27 is a view in side elevation of the apparatus shown in Fig. 26;--

Please replace the paragraph beginning at page 11, line 15, with the following rewritten paragraph:

--One aspect of the present invention is the use of an outer layer 12 of a material that can receive a high resolution diffraction relief 16, and retain that relief pattern reliably for the intended life of the product, under anticipated conditions of manufacture, handling, storage and use. In particular, it has been found that certain materials can be: (1) formed into solid outer layers or coatings around a core, (2) subsequently heated to soften (including liquefy) the layers, (3) molded to form a high resolution diffraction relief, and then (4) cooled to retain that relief pattern in a solid form when (5) released or de-molded. General characteristics of these materials are that they have a controllable water-stability, are heat-formable, and are capable of being applied to the dosage form by known pan coating, printing, or laminating techniques. Such materials advantageously also produce coatings that are resistant to cracking, wrinkling, and/or crystallizing, can be made to flow or bond at a temperature lower than that which will adversely effect the core, can retain a grating with a phase displacement on the scale of the wave length of light, are palatable, will not interfere with the release of the cores contents, and have controllable heat and water stability in storage so as to accurately control the fading or color. This controllable changes seen as a fading or color provides a readily visible indication of the environmental history of the dosage form, and its quality.--

Please replace the paragraph beginning after the table on page 13 with the following rewritten paragraph:

--The HPMC grades (e.g., "P5/6") above those of its manufacturer, Dow Chemical Co. "Spectraspray" is a trade description of a liquid colorant of Warner-Jenkins, Inc. "Marcoat" is a trade description of an aqueous shellac solution of Emerson, Inc. "DE 40" means "dextrose equivalency of 40%".--

Please replace the paragraph beginning after the table on page 15 with the following rewritten paragraph:

--In Examples 1 and 2 "Wt/ml" is the accumulated weight increase during the pancoating process in the dosage forms being coated, "ml" or "milliliter" being an approximate weight measure in grams given that one ml of water weighs one gram. Inlet and outlet Temp C are the air inlet and outlet temperatures to and from the coater in degrees Centigrade. "CFM" is cubic feet per minute of this air flow through the coater and "Atm Air PSI" is the air pressure in coater in pounds per square inch. "RPM" is revolutions per minutes, the speed at which the drum of the coater rotates. "Spray g/min" is the rate in grams per minute that the aqueous solution of the material being coated is sprayed into the drum of the coater. "Time minute" is the elapsed during operation of the pancoating for that coating.--

Please replace the paragraph beginning at line 8 after the table on page 16 with the following rewritten paragraph:

--The coated tablets were stored for 3 weeks at 85° F and 65% relative humidity (RH). After the three week period, the tablets still retained an 80-90% diffraction efficiency. Tablets stored at similar temperatures, but at 80% RH, reached the point at which the microrelief started to fade, i.e., the point at which changes in the image on effect it produced became visible and/or detectable.--

Please replace the paragraph beginning at page 18, line 7, with the following rewritten paragraph:

--In the above preferred examples the outer coating 12 comprised two complete coatings, both being applied using conventional rotating drum "pan" coaters for tablets. Colorants in the first coating produce a desired background color for the dosage form and provide contrast for the holographic image or effect produced by the microrelief. It is also possible to add color to the core before compression. Often the particle size of the aluminum lakes and titanium dioxide utilized in the first coating--if not fine enough--can interfere with the transfer process by sticking to the mold. This results in spotty, ineffective patterns. Thus, preferably, only the undercoat or the core carries a colorant; the overcoat is clear, and it is more stable.--

A12

Please replace the paragraph beginning at page 19, line 28, with the following rewritten paragraph:

--Layers 12 formed of these materials are used to enclose the cores as in pan coating, or partially enclose a section of the core, as when they are applied using known printing or lamination techniques. If the layers themselves are formed into sections, the sections themselves can be used as dosage forms after being made to absorb therein the contents of the pharmaceutically active agent, as described below in more detail with reference to Fig. 10.--

A13

Please replace the paragraph beginning at page 20, line 15, with the following rewritten paragraph:

--A particular feature of a preferred embodiment of the invention is that the faces 18 as shown in Figs. 1-12 are characterized by 1) a shallow, convex curvature, generally along a circular arc as shown, or 2) a small flat recess. In general it is more difficult to transfer onto and then reconstruct a microrelief on a curved surface than a flat surface. Functionally, the degree of the curvature and the amount of the flat area at the outer surface of the dosage form should be such so as to resist the twinning of tablets during the coating process and allow for a good diffraction relief to be created (the pattern of ridges and grooves in the layer 12) and reconstructed (the viewed hologram). As a

A14

functional test of the appropriate degree of twinning, preferably twinning should be controlled to limit rejected twinned tablets to less than 0.5% of the total yield. As a functional test of the appropriate degree of pattern reconstruction, preferably diffraction efficiency should be not less than 80%. Increase of pan-coating rotation speed (RPM), spray rate (g/min), run time, as well as inlet and exhaust temperature and air pressure in the coater, all affect the amount of flat area and/or degree of shallowness of curvature that can be used before twinning affects limit yield. Preferred speeds rates and temperatures are described in the above examples.--

Please replace the paragraph beginning at page 22, line 24, with the following rewritten paragraph:

--Figs. 6 - 6C show yet another embodiment for a dosage form 10 in the form of a tablet with a core 14 coated with a layer 12 and having rounded shoulders 18b and a central recess 24 to control twinning, all according to the present invention. The Figs. 6 - 6C embodiments differ from the Fig. 5-5C embodiment principally in that the lettering 22 projects down rather than up in the central recess 26. Fig. 6C is a detailed sectional view taken along line C-C in Fig. 6 to illustrate the configuration of the recesses and the relative heights thereof. A microrelief 16 is typically formed in the layer 12 covering section 24. It may also be thermoformed in the surrounding bottom surface as well as the flat surface 18a surrounding both recesses 24 and 26. While the double recess dosage form configuration is more complex, it has the advantage of providing a flat surface 26 to receive a diffraction relief 16, while at the same time accenting the area around lettering 22. For purposes of illustration only, the dosage form shown in Figs. 6 - 6C, with the same general configuration and dimensions as the dosage forms shown in Figs. 4 and 5, has a maximum depth in the first recess 24 of approximately 0.0054 inch, and a the maximum depth of the second recess of approximately 0.0064 inch. As before the depth of the recess into which the microrelief is transferred also helps to protect it from abrasion. Again, these values are merely illustrative, and in no way should be construed as limiting the scope of this invention to that particular value, or even a near range of values.--

Please replace the paragraph beginning at page 25, line 24, with the following rewritten paragraph:

A16

--Fig. 12C shows a tablet 10 using a combination of the grooves 19 and 19'.--

Please replace the paragraph beginning at page 26, line 20, with the following rewritten paragraph:

A17

--The transfer plate 32 is preferably formed as a thin, temperature resistant sheet of a material that can retain a high resolution microrelief such as a diffraction pattern on its outer surface, which is preferably thermally conductive and able to flex sufficiently to transfer the relief to a heat-softened and/or liquefied layer 12 on one face 18 (Figs. 1-12H) of dosage form 10 while accommodating to its shape. The preferred material is a diffractive surface composed of an electroformed metal or a heat resistant plastic, both with a thickness in the range of 1 to 5 mils. The tension in the transfer plate 32 produces a downward pressure urging the microrelief pattern on the transfer plate to be replicated in the layer 12 on the dosage forms as they pass through a nip defined by the belt 34 (at the roll 36a) and the opposed portion of the transfer plate 32.--

Please replace the paragraph beginning at page 28, line 3, with the following rewritten paragraph:

A18

--Figs. 16 and 17 show an alternative apparatus 45 according to the present invention which, like the apparatus 30 of Figs. 13-15, uses two transfer plates 46, 46' to replicate a high resolution diffraction relief on opposite faces 18 of dosage forms 10 carried in opening 48 of moving conveyor belt 50. The upper rim of belts 50 moves right to left, as shown, as dosage forms 10 are fed into the openings 48 which aligns and transports the dosage forms. The openings 48 extend through the belt 50. A panel 52 - - or a belt or other equivalent member - - supports the dosage forms at their bottom to

retain them in the openings 48 before and after the transfer plates 46, 46'. The transfer plates 46, 46' are each journalled on rolls 54a, 54b that drive the transfer plates in coordination with the movement of the belt 50. The transfer plates sandwich the dosage forms there between. Rolls 55 disposed behind each transfer plate adjacent the dosage forms are heated to heat the dosage forms through the transfer plates to a suitable temperature, again, preferably 90°C to 150°C. Cooling rollers 56 then help in demolding. Note that the thinness of the transfer plates not only facilitates rapid heat transfer, but also facilitates the application of a generally uniform pressure over the dosage form surface receiving the microrelief, despite the fact that the surface might not be flat, e.g., the curved surfaces 18 of the dosage forms 10 shown in Figs. 1-2. A uniform distribution of the pressure can be promoted by using a resilient pressure member, e.g., a foam sleeve on alternating rolls 54 and 54', and 56 and 56' below the dosage form such that each heating or cooling roller is pressing the bottom or top of the dosage form against an opposing resilient pressure member.--

Please replace the paragraph beginning at page 30, line 22, with the following rewritten paragraph:

--Fig. 25 shows a rotary apparatus 108 for thermoforming a high resolution diffraction relief onto a layer 12 on an array of dosage forms 10 carried in a pallet 71. A diffraction pattern transfer plate 76 is placed on each incoming pallet 71 at 110. The pallet is then transported to a position 112 where it is gripped between a pair of members 114, 116 each supported on the end of an arm 118 rotated by a hub 120. At least one arm 118 of each pair of pivots to open, close, and press the transfer plate towards the dosage forms. As the hub rotates, a gripped assembly is heated and pressed at angular position 119, cooled at position 121, and released by opening the members 114, 116 at position 122 where the assembly is transported to a de-molding and transfer plate removal station 124.--